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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
ROSARIO LIZIO, ET AL.	: EXAMINER: WESTERBERG, N. M.
SERIAL NO: 10/564,096	:
FILED: MAY 2, 2006	: GROUP ART UNIT: 1618

FOR: MULTIPARTICLE PHARMACEUTICAL DOSAGE FORM CONTAINING A MUCOADHESIVELY FORMULATED PEPTIDE OR PROTEIN ACTIVE SUBSTANCES METHOD FOR PRODUCING SAID PHARMACEUTICAL DOSAGE FORM

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

REPLY BRIEF UNDER 37 CFR § 41.41

This Reply Brief is timely filed April 22, 2010, with no extension of time. This Reply Brief responds to the erroneous findings and conclusions in the Examiner's Answer dated February 22, 2010 (Ans.).

With all due respect, the Examiner's Answer does not undermine the arguments, interpretation of the claim language, and/or supporting evidence relied upon in the Appeal Brief. To the contrary, the Examiner rigidly adheres to erroneous findings and conclusions that:

(1) Watts' inner matrix layer necessarily suggests "an inner matrix layer consisting essentially of a mucoadhesive polymer having a mucoadhesive effect, into which is embedded a peptide or protein" (Claim 1) because it comprises "chitosan";

(2) Watts' inner matrix layer necessarily suggests "an inner matrix layer comprising . . . an active pharmaceutical ingredient and a polymer having a [defined] mucoadhesive effect" because it comprises "chitosan" (Claim 34);

(3) Shimono necessarily describes "an inner matrix layer comprising . . . an active pharmaceutical ingredient and a polymer having a [defined] mucoadhesive effect" because it comprises an active ingredient-containing core surrounded by a water-insoluble polymer having "chitosan" dispersed therein (Claim 34);

(4) Shimono and Watts are necessarily combinable and would have suggested the specific forms and compositions Applicant claims because both describe a matrix containing "chitisan"; and

(5) Applicant's claims necessarily contain new matter because the supporting specification does not recite all their limitations in the exact same terms.

It is well recognized that a prima facie case of unpatentability must be revisited and reconsidered in light of all Applicant's arguments and evidence to the contrary. *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). Here, the Examiner does not reconsider his evidentiary findings, the weight of the evidence or record, his interpretations of the claim language, and/or his conclusions of law regardless of the strength of Applicant's evidence and/or arguments to the contrary. This inflexibility itself constitutes reversible error.

STATUS OF THE CLAIMS

Claims 1, 3, 4, 6-11, and 33-35 stand twice rejected under 35 U.S.C. § 103. The rejections are APPEALED.

Claim 34 stands twice rejected under 35 U.S.C. § 102. The rejection is APPEALED.

Claims 33 and 34 stand twice rejected under 35 U.S.C. § 112, 1st ¶ (written description requirement). The rejections are APPEALED.

Claims 1, 3, 4, 6-11, and 33-35 are APPEALED.

Claims 2, 5 and 12-32 have been withdrawn from consideration by the Examiner.

STATUS OF AMENDMENTS

No amendment to Claims 1, 3, 4, 6-11, and 33-35 has been submitted or entered after the Examiner's June 22, 2009, final rejections thereof.

GROUNDS OF REJECTION TO BE REVIEWED

A. The rejection of Claims 1, 3, 4, 6-11, and 34 under 35 U.S.C. §103 over Watts (U.S. Patent No 6,465,626, issued October 15, 2002). Claims 1, 3, 4, and 6-11 must be separately considered from Claim 34.

B. The rejection of Claims 1, 3, 4, 6-11, and 34 under 35 U.S.C. §103 over Watts in view of Berliner (U.S. Patent No. 5,849,327, issued December 15, 1998). Claims 1, 3, 4, and 6-11 must be separately considered from Claim 34.

C. The rejection of Claims 1, 3, 4, 6-11, and 34 under 35 U.S.C. §103 over Watts in view of Engel (U.S. Patent No. 5,773,032, issued June 30, 1998). Claims 1, 3, 4, and 6-11 must be separately considered from Claim 34.

D. The rejection of Claim 34 under 35 U.S.C. §102 as anticipated by Shimono (EP1203590 A1, published May 8, 2002).

E. The rejection of Claims 1, 4, 33 and 34 under 35 U.S.C. §103(a) over Shimono in view of Watts. Claims 1, 4, and 33 must be separately considered from Claim 34.

F. The rejection of Claims 1, 4, 9, 10, and 33-35 under 35 U.S.C. §103 over Shimono in view of Watts and Engel. Claims 1, 4, 9, 10, and 33 must be separately considered from Claims 34-35.

G. The rejection of Claim 34 under 35 U.S.C. 112, 1st ¶, for lack or written description.

H. The rejection of Claim 33 under 35 U.S.C. 112, 1st ¶, for lack or written description.

ARGUMENT

1. Claim Interpretation

The pellets of Applicant's claimed form (Claims Appendix; Claim 1) comprise:

(1) "an inner matrix layer consisting essentially of a mucoadhesive polymer having a mucoadhesive effect, into which is embedded an active substance" (Claims Appendix, Claim 1);

(2) "so that the active substance-containing, mucoadhesive matrix layer is exposed to and binds to the intestinal mucosa and releases the active substance there" (Claims Appendic, Claim 1): and

(3) "wherein the polymer having a mucoadhesive effect exhibits a mucoadhesive effect" (Claim 1).

The pellets of Claim 1 do not comprise:

(a) an inner matrix layer consisting essentially of a mucoadhesive polymer NOT having a mucoadhesive effect, into which is embedded an active substance;

(b) so that the active substance-containing, BIOADHESIVE matrix layer is exposed to and binds to the intestinal MUCOSAL MEMBRANE and releases the active substance there; and

(c) wherein the polymer having a mucoadhesive effect DOES NOT EXHIBIT A MUCOADHESIVE EFFECT.

The Examiner's interpretation of the scope and content of the claims is inconsistent with the claim language itself and the teaching throughout the Specification. While claims are to be given their broadest reasonable interpretation, that interpretation must be reasonably consistent with the teaching in the supporting specification. *In re Sneed*, 710 F.2d 1544, 1548 (Fed. Cir. 1983).

Applicant's Specification does not teach that a mucoadhesive polymer has the bioadhesive effect Watts attributes to its polymers comprising no less than 50% gelatin and no more than 50% chitosan. Watts' polymers comprising at least 50% gelatin have a bioadhesive effect. Shaheen (Evidence Appendix, Other Evidence) teaches (Shaheen, p. 504, col. 1), "The term bio-adhesive describes materials that bind to biological substrate such as, mucosal membrane." Shaheen's Figure 4 (Shaheen, p. 507, col. 2, Fig. 4) shows that gelatin is a bioadhesive which releases increasing percentages of theophylline for at least 8 hours. Shaheen concludes (Shaheen, pp. 507-508, bridging ¶; emphasis added):

> Bio-adhesive polymers like . . . Gelatin . . . were evaluated in sustaining the drug release from their respective tablets. . . . Gelatin also showed concentration dependent TH release . . . .

The English Abstract of WO 93/13753, published July 22, 1993, of record, consistently teaches (emphasis added):

> Described are pellets containing peptide drugs incorporated in a matrix consisting of gelatin or fractionated gelatin and plasticizers, the pellets having a semi-solid to gel-like consistency. Such drug forms exhibit, after application, bioadhesive properties and, by virtue of the matrix materials specified, allow or enhance the resorption of the peptide drug by the body.

On the other hand, the pellets comprising Applicant's claimed composition (Claims Appendix; Claim 34) comprise:

(4) "an inner matrix layer comprising . . . an active pharmaceutical ingredient and a polymer having a mucoadhesive effect" (Claims Appendix, Claim 34);

(5) "an outer coating of an anionic polymer or anionic copolymer" (Claims Appendix, Claim 34): and

(6) "wherein said particles do not have a layer separating the inner matrix and outer coating" (Claims Appendix, Claim 34).

The pellets of Claim 34 do not comprise:

(a) an inner matrix layer comprising an active pharmaceutical ingredient and a polymer NOT having a mucoadhesive effect;

(b) an outer coating of an anionic polymer or anionic copolymer" (Claim 34): and

(c) wherein said particles HAVE a layer separating the inner matrix and outer coating.

2. The Examiner erred rejecting Claims 1, 3, 4, 6-11, and 34 under 35 U.S.C. § 103 in view of Watts, optionally in view of Berliner or Engel

Watts teaches (Watts, col. 5, ll. 43-51):

> The microparticles will consist of preferably between 50 to 95%, or preferably between 70 and 90% and most preferably between 75 and 85% of the type A gelatin, and correspondingly between 50 and 5%, preferably between 30 and 10% and most preferably between 25 and 15% of chitosan . . . .

Watts explains (Watts, col. 7, ll. 2-4; emphasis added): "The compositions may gel on the mucosa at least to some extent and this may facilitate retention of the composition on the mucosa."

Watts teaches that its combination gels on the mucosal membrane at least to some extent, helps retain the composition on the mucosa, and improves and prolongs the

presentation of the active substance to the mucosal surfaces to an extent and effect superior to that produced by either chitosan or gelatin alone. Watts' combination of at least 50% gelatin and at most 50% chitosan, preferably 70 to 90% gelatin and 30 to 10% chitosan, binds to and is retained by the surface of the mucosal membrane to an extent superior to gelatin itself and therefore must have an overall bioadhesive effect. Thus, persons having ordinary skill in the art would have understood that Watts' compositions do not comprise a polymer having a mucoadhesive effect, and thus present a substantial risk of toxicity and side effects such as irritation and infection. English Abstract of WO 93/13753, published July 22, 1993, confirms that a matrix of gelatin or fractionated gelatin exhibits "bioadhesive properties". Shaheen also confirms that gelatin is a bioadhesive polymer which binds to the mucosal membrane, is retained by the mucosal membrane, and continuously releases the active agent for at least 8 hours.

Nevertheless, despite the claim express language of Applicant's claims and the wealth of teaching in Applicant's Specification, Watts, Shaheen, and WO 93/13753 to the contrary, the Examiner erroneously finds:

(i) Since both Watts' composition and Applicant's claimed composition deliver active ingredients following oral administration, both compositions have the "same activity" (Ans., pp. 12-13, bridging ¶).

(ii) "The addition of gelatin . . . does not 'materially affect" the delivery of the pharmaceutically active ingredients" (Ans., pp. 12-13, bridging ¶).

(iii) "There is no requirement in the claim that the [embedded] dosage form . . . be bioadhesive or mucoadhesive, only that a polymer having a mucoadhesive effect . . . is present" (Ans., p. 13, 1st full ¶);

(iv) "Whether the dosage form as a whole is bioadhesive or mucoadhesive is not relevant as those features are not recited in the instant claims" (Ans., pp. 14-15) and

(v) "As the cited prior art does not covalently modify the chiosan with gelatin, . . . simple mixing of chitosan with gelatin will not alter the physical properties of the chitosan so as to render the chitosan non-mucoadhesive and/or not have the mucoadhesive effect" required in the instant claims (Ans., pp. 14-15, bridging ¶)

With all due respect, the evidence of record indicates that the Examiner's findings are clearly erroneous.

Moreover, whether the polymer itself or the dosage has a mucoadhesive effect, Watts' combination of at least 50% gelatin and at most 50% chitosan clearly does not have a mucoadhesive effect. Watts' combination of at least 50% gelatin and at most 50% chitosan has a bioadhesive effect. Neither Berliner nor Engle remedy Watts' deficiencies with regard to the mucoadhesive polymer having a mucoadhesive effect required by Applicant's claims.

Nor is the inner matrix of Applicant's claimed form or composition open to at least 50% gelatin. Applicant's claimed pellets comprise an inner matrix layer "consisting essentially of" a mucoadhesive polymer having a mucoadhesive effect" or "an inner matrix comprising a polymer having a [defined] mucoadhesive effect". No composition Watts discloses or reasonably suggests includes either a polymer or polymer composition which has "a mucoadhesive effect". To the contrary, Watts teaches that its combination of at least 50% gelatin and at most 50% chitosan binds to, and is retained by, the mucosal surface to an extent superior to either gelatin or chitosan alone (Watts, col. 4, ll. 1-10). When combined with gelatin, the combination of gelatine and chitosan appears to have bioadhesive properties and binds to the mucosal membrane. Applicant's Claim 1 requires that the "mucoadhesive

matrix layer is exposed and binds to the intestinal mucosa and releases the active substance there" (Claims Appendix, Claim 1).

Persons having ordinary skill in the art would have understood from Watts' teaching that bioadhesive binding to the mucosal membrane is preferred and required. Watts would have directed persons having ordinary skill in the art away from Applicant's invention. As said in *KSR Int'l Co. v. Telflex Inc.*, 550 U.S. 398, ___ (2007), "[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious."

The Examiner's rejection of Claims 1, 3, 4, 6-11, and 34 under 35 U.S.C. § 103 over Watts, optionally in view of Berliner or Engel, should be reversed.

3. The Examiner clearly erred rejecting Claim 34 under 35 U.S.C. § 102 as anticipated by Shimono

Shimono teaches [0007; 0008; emphasis added]:

> [A] solid preparation containing chitosan powder, which can release the medicament specifically in the large intestine and control the release of the medicament in the large intestine . . . [is] obtained by coating successively a medicament-containing solid material with (1) a water-insoluble polymer having a chitosan powder dispersed therein, and (2) an enteric polymer.

Shimono's water-insoluble coating film consisting of chitosan and a water-insoluble polymer is formed "around the [medicament-containing] core" [0027; emphasis added]. The film is not a matrix for the active ingredient-containing core. An enteric coating subsequently may be formed around the water-insoluble coating film [0027]. At no time is the medicament-containing material ever embedded in the mucoadhesive chitosan as is required by Applicant's Claim 1. Moreover, the medicament-containing material is never combined with chitosan in an inner matrix as is required by Applicant's Claim 34 and described in Applicant's Specification.

Shimono teaches [0019; 0020]:

> [T]he compounding ratio of the chitosan powder to the water-insoluble polymer may be in any possible range, but preferably in the range of about 1:20 to about 20:1, more preferably in the range of about 1:10 to about 10:1, and especially preferably in the range of about 1:4 to about 4:1.

Shimono's medicament is not present in an inner matrix comprising the medicament and chitosan. Shimono's medicament is separated from the chitosan by the water-insoluble polymer. Interpreted in light of Applicant's supporting Specification, as it must be interpreted, the inner matrix of Applicant's claimed form is a matrix comprising both the active substance and chitosan.

However, the Examiner finds, inconsistent with the teaching in Applicant's Specification, that Applicant's inner matrix may be a medicament core coated with a coating of chitosan dispersed in a water-insoluble polymer. Even though Shimono's dispersed chitosan particles appear to be separated from the "medicament-containing solid material" by the water-insoluble polymer (Shimono, p. 21, Figure 11), the Examiner nevertheless concludes that the claimed inner matrix may comprise two separate and distinct layers. To the contrary, Applicant's Claim 34 requires an inner matrix comprising an active ingredient and a polymer having a mucoadhesive effect (Claims Appendix, Claim 34). As defined in Applicant's Specification, an "inner matrix" (Spec., p. 6, ll. 35-39; emphasis added):

> . . . acts as active substance carrier. The inner matrix layer additionally has the function of binding the active substance, by means of the contained mucoadhesive polymer, to the intestinal mucosa . . .

A mucoadhesive polymer dispersed in a water-insoluble polymer layer which is separated from the active ingredient is not an "inner matrix" which acts as a carrier for the active ingredient and binds it.

Moreover, there is no evidence or suggestion in Shimono that the combination of chitosan and the water-insoluble polymer in Shimomo's first coating either has or exhibits a mucoadhesive effect when combined in the ratios indicated. To the contrary, persons having ordinary skill in the art reasonably would have expected that, like the gel-forming,

bioadhesive gelatin, hydroxypropyl methylcellulose, sodium carboxymethyl cellulose, and xanthan gum matrices described in Watts, Shaheen, and WO 93/13753, Shimono's combination of water-insoluble polymer and chitosan would be more likely to exhibit bioadhesive binding characteristics.

As evidence suggesting that Shimono's combination of a chitosan dispersed in a water-insoluble polymer has a bioadhesive effect rather than a mucoadhesive effect, Shinono teaches that its water-insoluble polymer is not readily eliminated or flushed from the intestine. Shimono's preparations are "sustained release solid preparation[s] containing a chitosan powder" [0007; emphasis added]. Shimono's preparation "provides a sustained release solid preparation for producing the . . . colonic delivery solid preparation containing chitosan powder [0008; emphasis added]. Contrary to Applicant's claimed composition, the compositions described by Shaheen, Watts, and Shinomo are all sustained release compositions which retain a medicament-containing carrier in the intestine for substantial periods of time. Applicant's inner matrix comprising an active substance and a polymer having a mucoadhesive effect binds to the mucus or mucin. Applicant's composition is not retained in the intestine in solid form for substantial periods of time and would not be considered "a sustained release solid preparation" of the kind described by Shaheen, Watts, and Shinomo. Bioadhesive materials are sustained release solid preparations. Dissolution or disintegration of Shimono's water-insoluble polymer is not likely to occur in the 15 minutes required by Applicant's Claim 34.

The PTO has not shown that Shimono describes every element of the subject matter defined by Applicant's Claim 34.

4. The Examiner erred rejecting Claims 1, 4, 9, 10, and 33-35 under 35 U.S.C. § 103 over Shimono in view of Watts, optionally further in view of Engel

Shimono describes a sustained release composition comprising a medicament-containing core which is coated with a water-insoluble polymer in which chitosan particles

are dispersed. An outer layer of an enteric coating may be applied thereover. Watts describes pharmaceutical compositions with an inner matrix comprising an active substance and a mixture comprising at least 50% gelatin and no more than 50% chitosan (Watts, col. 4, l. 1, to col. 5, l. 51). Neither Shimono nor Watts describes an inner matrix comprising an active substance and a mucoadhesive polymer having a mucoadhesive effect as Claims 1 and 34 require. Watts' mixture of gelatin and chitosan forms an inner matrix which is bioadhesive, i.e., it binds to and is retained by the mucosal membrane for substantial periods of time. Watts' inner matrix does not comprise an active substance and a polymer having a mucoadhesive effect of at least η_β of 150 to 1,000 mPa·s and a water uptake ranging from 10 to 750% in 15 min at a pH between 4.0 to 8.0 (Claim 1) or 5.5 to 7.2 (Claim 34). Watts neither describes nor reasonably suggests the subject matter Applicant claims.

Watts' delivery compositions comprising gelatin and chitosan appear to be bioadhesive compositions having a bioadhesive effect. Shimono's delivery compositions also appear to be sustained release, bioadhesive compositions. Where is Applicant's claimed mucoadhesive effect?

Significantly, neither Watts nor Shimono discloses an inner matrix core "consisting essentially of" the active ingredient and a mucoadhesive polymer having a mucoadhesive effect which Applicant's Claim 1 requires. There is no reasonable basis for rejecting Applicant's Claim 1 over the combined teachings of Shimono and Watts. The combined teachings would not have led a person having ordinary skill in the art to any invention Applicant claims.

Significantly, the Examiner does not contradict the evidence relied upon by Applicant in support of patentability. Rather, the Examiner suggests that (1) Applicant's claims are far broader in scope than the claim language indicates, (2) the mucoadhesive polymers in the inner matrix need not have a mucoadhesive effect contrary to the express claim language, (3)

the inner matrix comprising active ingredient and mucoadhesive polymer need not carry and/or bind the active agent in the manner the Specification requires, (4) the mucoadhesive polymers may bond to the mucosal membrane and sustain release contrary to Applicant's teaching, and (5) the mucoadhesive polymers need not be readily and regularly flushed from one's system contrary to the express purpose of Applicant's invention. In short, the Examiner's rejections of Claims 1, 4, 33, and 34 under 35 U.S.C. § 103 over Shimono in view of Watts should be reversed.

Engel does not remedy any of the deficiencies of Shimono and Watts.

5. The Examiner erred rejecting Claim 34 under 35 U.S.C. § 112, 1st ¶

At page 37, line 35, of the Specification, the paragraph is entitled "**Lipophilic matrix/polymers having a mucoadhesive effect**". That title, on its face, refers to a lipophilic matrix or polymers having a mucoadhesive effect. A lipophilic matrix is "preferred," not necessarily present in the compositions disclosed (Spec., pp. 37-38, bridging ¶). Accordingly, the Specification indicates that it may be excluded. If Applicant's Specification reasonably describes an "inner matrix layer consisting essentially of a polymer having a mucoadhesive effect and an active substance embedded therein" (Claims Appendix, Claim 1), and the Specification clearly teaches that the inner matrix may comprise a lipophilic matrix (Spec., pp. 37-42), the Examiner has not explained why the Specification does not adequately describe a composition containing pellets that comprise the preferred "mucoadhesive lipophilic matrix" and particles that "do not have a mucoadhesive lipophilic matrix embedded in the inner matrix" as recited in Claim 34.

The Examiner said (Ans., p. 22, 2nd full ¶):

> In looking at the paragraph which follows the heading, it is clear that "lipophilic matrix/polymers having a mucoadhesive effect" refers to two separate items, a lipophilic matrix and polymers having a mucoadhesive effect . . . .

Compliance with the written description requirement of 35 U.S.C. § 112, 1st ¶, is based on the Specification as a whole. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). The Examiner's finding and rejection is based exclusively on a single paragraph of the Specification. The Examiner has not explained why the written description requirement for the Specification as a whole has not been satisfied.

6. The Examiner erred rejecting Claim 33 under 35 U.S.C. § 112, 1st ¶

Admittedly, the Specification does not expressly describe a composition that "does not contain gelatin" in its inner matrix layer in those precise words. It need not do so. In re Kaslow, 707 F.2d 1366 (Fed. Cir. 1983). However, Applicant's Specification provides examples of pellets wherein the inner matrix does not contain gelatin.

Applicant's disclosure shows that Applicant had possession of the claimed composition wherein the inner matrix does not contain gelatin at the time the Application was first filed. Therefore, the invention of Claim 33 is described in the supporting examples and the Specification as a whole. The inventor most certainly invented the subject matter claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563-64.

However, the Examiner finds (Ans., p. 23, 1st full ¶):

> [T]hose examples are insufficient to support the exclusion of gelatin from all formulations, just as the specification would not support a limitation such as the pharmaceutical form does not contain eye of newt, even though none of the examples contain eye of newt.

The problem with the Examiner's statement is that all the Examiner's rejections in this case over Watts' disclosure are based on the presumption that the inner matrix of the pellets of the claimed multiparticulate pharmaceutical form may or may not include gelatin, when read and fully considered in light of the supporting Specification. The examples in this Specification , of course, show that the pellets of the claimed multiparticulate pharmaceutical form do not contain gelatin. In this case, the examples in this Specification would have taught persons having ordinary skill in the art with knowledge of the pertinent art that the pellets of the

claimed multiparticulate pharmaceutical form do not contain gelatin. Accordingly, the Examiner's rejection of Claim 33 under 35 U.S.C. § 112, 1st ¶, should be reversed.

CONCLUSION

For the reasons stated herein:

A. The rejection of Claims 1, 3, 4, 6-11, and 34 under 35 U.S.C. §103 over Watts (U.S. Patent No 6,465,626, issued October 15, 2002) should be REVERSED.

B. The rejection of Claims 1, 3, 4, 6-11, and 34 under 35 U.S.C. §103 over Watts in view of Berliner (U.S. Patent No. 5,849,327, issued December 15, 1998) should be REVERSED.

C. The rejection of Claims 1, 3, 4, 6-11, and 34 under 35 U.S.C. §103 over Watts in view of Engel (U.S. Patent No. 5,773,032, issued June 30, 1998) should be REVERSED.

D. The rejection of Claim 34 under 35 U.S.C. §102 as anticipated by Shimono (EP1203590 A1, published May 8, 2002) should be REVERSED.

E. The rejection of Claims 1, 4, 33 and 34 under 35 U.S.C. §103(a) over Shimono in view of Watts should be REVERSED.

F. The rejection of Claims 1, 4, 9, 10, and 33-35 under 35 U.S.C. §103 over Shimono in view of Watts and Engel should be REVERSED.

G. The rejection of Claim 34 under 35 U.S.C. 112, 1st ¶, for lack or written description should be REVERSED.

H. The rejection of Claim 33 under 35 U.S.C. 112, 1st ¶, for lack or written description should be REVERSED.

All the findings and conclusions represented in the Examiner's Answer having been traversed in the main Appeal Brief filed November 20, 2010, and/or this Reply Brief, all the appealed rejections fairly should be reversed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon

Customer Number
22850

Richard L. Treanor
Attorney of Record
Registration No. 36,379

Teddy S. Gron
Registration No. 63,062